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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,397	03/09/2004	Robert Falotico	CRD-5068	1881

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EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,397	FALOTICO ET AL.	
	Examiner	Art Unit	
	Casey S. Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination filed 5/19/2008 and Amendment/Remarks filed 4/2/2008.

Receipt is also acknowledged of the employment agreements submitted on 4/2/2008.

Claims 12-24 have been cancelled. Claims 1-11 are pending. No claim amendments were submitted. It is noted that claim 9 includes markings that are characteristic of an amended claim but it is apparent that the claim was copied from the previous "amended" claim set dated 11/15/2007 and no new amendments were made. Also, applicant's Remarks and claim identifier clearly indicate that the claim was not amended. Thus, while the application is technically non-compliant, in the interest of expediting prosecution, the examiner is deeming the error obvious and typographical in nature. As such, it is requested that applicant correct the typographical error in the next correspondence.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 2/4/2008:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1).

Borges teaches coating an implantable medical device with a composition comprising a basecoat and a topcoat, wherein the basecoat includes at least one active agent that is incorporated into a first polymeric material, the basecoat is affixed to the surface of the medical device, and the topcoat contains a second polymeric material which is affixed to the basecoat for the purpose of controlling the elution rate of the at least one active agent (paragraph [0027]). Borges teaches a particular embodiment where the basecoat comprises a fluoropolymer and rapamycin and the topcoat comprises an acrylic polymer (paragraph [0030]). Borges also teaches the particular medical devices, stents, anastomosis devices and stent-grafts (abstract; paragraph [0032]). Borges further discusses drug combination therapy mainly for the treatment of

restenosis and lists possible drugs that may be employed in the invention including rapamycin, cladribine and etoposide (paragraphs [0085]-[0087]).

Borges is silent to the particular drug combination of rapamycin and a topoisomerase I inhibitor.

Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs selected from the group consisting of a finite amount of particular drugs including topoisomerase I inhibitors including adriamycin etoposide, irinotecan and hycamptin (topotecan) as well as rapamycins (abstract; paragraphs [0020] and [0022]).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. Both references teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor and a rapamycin. Thus, in Borges, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular anti-restenosis drug combination of a rapamycin and a topoisomerase I inhibitor such as iriniotecan or topotecan as suggested by Fischell.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Wrenn (USPN 6,485,514 B1).

Borges and Fischell teach the elements discussed above.

The references are silent to the particular topoisomerase I inhibitor, camptothecin.

Wrenn teaches an implantable medical device coated with a composition comprising camptothecin for the treatment of restenosis (claim 1).

One skilled in the art would look to Wrenn because Wrenn teaches that camptothecin is an effective compound for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as the topoisomerase I inhibitor camptothecin and a rapamycin. Thus, in Borges and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin as suggested by Wrenn.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Eury et al. (US 2002/0004679 A1).

Borges and Fischell teach the elements discussed above.

The references are silent to the particular topoisomerase I inhibitors, camptothecin and DX-8951f.

Eury teaches an implantable medical device coated with a composition comprising a topoisomerase I inhibitor for the treatment of restenosis (abstract; paragraph [0045]). A preferred topoisomerase I inhibitor is camptothecin and analogues thereof including DX-8951f, iriniotecan and topotecan (paragraphs [0035] and [0036]).

One skilled in the art would look to Eury because Eury teaches that topoisomerase I inhibitors in general, and camptothecin and its analogues in particular, are effective compounds for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as camptothecin or an analogue thereof and a rapamycin. Thus, in Borges and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin or an analogue thereof as suggested by Eury.

Response to Arguments

Applicant's arguments with regards to rejection under 35 USC 103 over Borges and Fischell have been fully considered but they are not persuasive.

Applicant argues that the subject matter in the copending application '417 and the claimed invention were subject to an obligation of assignment to the same person (i.e., Cordis) and also provided employment agreements attempting to show an obligation to assign.

In response, it is respectfully submitted that 35 USC 103(c) states,

> (c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> (2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if —
>
> (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
>
> (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
>
> (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.
>
> (3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

The examiner agrees that a showing of obligation to assign is permissible. However, the obligation must be at the time that the claimed invention was made. Applicant must show that the entire invention was either commonly owned or under obligation at the time of the invention. Applicant submitted employment agreements for all three inventors (i.e., Falotico, Parry and Zhao) listed for the instant application; however applicant only submitted one employment agreement for inventor, Narayanan of '417.

There are 4 other inventors listed on '417 that are not accounted for. Also, as mentioned above, all inventors must be under obligation at the time the invention was made. There is nothing in the paperwork that verifies that the obligation was at the time of the invention. Further, the patent agreement for Narayanan, shows at the time of execution that there was an obligation to assign to Cordis. However, it does not show that Narayana was bound by the contract at the time of the invention, nor does it show that Corids was under obligation to assign to Johnson & Johnson at the time of the invention. For at least these reasons, applicant's arguments are found unpersuasive. Thus, the rejection is maintained.

NEW REJECTIONS

After further consideration, the following rejections have been newly added:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that applicant argues that the instant application and copending application 10/883,328 are commonly owned. See applicant's Remarks 4/2/2008 and 11/15/2007. In light of applicant's statements, the following rejection is presented.

Claims 1-3 and 6-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/883,328 in view of Fischell et al. (US 2003/0065382 A1).

The claims of the instant application are drawn to a medical device comprising:

an implantable structure;

a basecoat matrix comprising rapamycin and a topoisomerase I inhibitor which is incorporated into a first polymeric material; and

a top coat comprising a second polymeric material.

Claim 3 of copending application '328 is drawn to an implantable medical device comprising:

a tubular member that is insertable into the lumen of a vessel;

a basecoat matrix comprising a first polymeric material comprising polyvinylidenefluoride-co-hexafluoro propylene and at least one agent; and

a topcoat comprising a second polymeric material comprising poly(n-butylmethacrylate).

'328 also teaches suitable medical devices that may be employed for the invention include stents, grafts and anastomotic devices (Abstract).

'328 is silent to the combination of rapamycin and a topoisomerase I inhibitor.

Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs selected from the group consisting of a finite amount of particular drugs including topoisomerase I inhibitors including adriamycin etoposide, irinotecan and hycamptin (topotecan) as well as rapamycins (abstract; paragraphs [0020] and [0022]).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. Both Fischell and the copending application '328 teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor and a rapamycin. Thus, in copending application '328, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular anti-restenosis drug combination of a rapamycin and a topoisomerase I inhibitor such as iriniotecan or topotecan as suggested by Fischell.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included here can be found *supra* under the heading *Maintained Rejections*.

Claims 1-3, 6, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (US 2002/0123801 A1) in view of Fischell et al. (US 2003/0065382 A1).

Pacetti teaches an implantable device having a multiple layer drug release coating. Said multiple layer drug release coating comprises a drug reservoir, a rate reducing membrane and an optional primer (Figures 2A-2C; paragraphs [0012]-[0013], [0029], [0048] and [0065]). Each layer comprises a polymeric material. The polymers utilized in the drug reservoir are located at paragraph [0060] and the drugs utilized in the drug reservoir are located at paragraph [0058]). Said drugs are chosen for the purpose of mainly inhibiting cellular activity of smooth muscle cells or inhibiting the development of restenosis (paragraph [0057]). Also, Pacetti teaches a drug reservoir comprising two drugs (Figure 2C). Said rate reducing membrane may comprise an acrylic based polymer (paragraphs [0071] and [0077]). Said implantable device can be any suitable device used for the release of an active agent including stents and stent grafts (paragraph [0079]).

Pacetti is silent to the combination of rapamycin and a topoisomerase I inhibitor.

Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs selected from the group consisting of a finite amount of particular drugs including topoisomerase I inhibitors such as adriamycin

etoposide, irinotecan and hycamptin (topotecan) as well as rapamycins (abstract; paragraphs [0020] and [0022]).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. Both Fischell and Pacetti teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor and a rapamycin. Thus, in Pacetti, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular anti-restenosis drug combination of a rapamycin and a topoisomerase I inhibitor such as iriniotecan or topotecan as suggested by Fischell.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (US 2002/0123801 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Wrenn (USPN 6,485,514 B1).

Pacetti and Fischell teach the elements discussed above.

The references are silent to the particular topoisomerase I inhibitor, camptothecin.

Wrenn teaches an implantable medical device coated with a composition comprising camptothecin for the treatment of restenosis (claim 1).

One skilled in the art would look to Wrenn because Wrenn teaches that camptothecin is an effective compound for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as the topoisomerase I inhibitor camptothecin and a rapamycin. Thus, in Pacetti and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin as suggested by Wrenn.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (US 2002/0123801 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Eury et al. (US 2002/0004679 A1).

Pacetti and Fischell teach the elements discussed above.

The references are silent to the particular topoisomerase I inhibitors, camptothecin and DX-8951f.

Eury teaches an implantable medical device coated with a composition comprising a topoisomerase I inhibitor for the treatment of restenosis (abstract; paragraph [0045]). A preferred topoisomerase I inhibitor is camptothecin and

analogues thereof including DX-8951f, iriniotecan and topotecan (paragraphs [0035] and [0036]).

One skilled in the art would look to Eury because Eury teaches that topoisomerase I inhibitors in general, and camptothecin and its analogues in particular, are effective compounds for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as camptothecin or an analogue thereof and a rapamycin. Thus, in Pacetti and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin or an analogue thereof as suggested by Eury.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615